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SUBSTANTIAL EQUIVALENCE SUMMARY

Safety and Effectiveness Studies of the Equinox catheter

Biological and performance studies have been completed to evaluate the safety and performance of the Equinox catheter. The studies were designed to:

- Verify the ability of the Equinox catheter to withstand the expected clinical conditions of use;
- Evaluate the performance of the Equinox catheter to safely advance into the peripheral and neuro vasculature;
- Evaluate the performance of the Equinox catheter to provide safe and effective temporary occlusion of the peripheral and neuro vasculature; and,
- Identify any new or unforeseen safety issues attributable to the Equinox catheter design technology and performance characteristics.

Safety and Effectiveness Results

- Biological safety has been demonstrated based on results of studies conducted in accordance with ISO and FDA guidelines for external communicating devices, circulating blood, with limited exposure time.
- Performance studies confirmed that the Equinox catheter was either equivalent to, or exceeded the performance requirements of consensus standards and guidance documents in all tests designed to verify safety and effectiveness of the device.
- Comparative test results confirmed that the Equinox catheter performance was substantially equivalent to the predicate device.

Substantial Equivalence

Based on the safety and performance data presented, MTI believes the Equinox catheter to be as safe and effective as the predicate device; and therefore, substantially equivalent to the predicate device, in that:

- The Equinox catheter has the same intended use as the predicate device;
- Scientific methods have been applied, and data presented to demonstrate that technical differences in construction of the Equinox catheter have not diminished safety or effectiveness; and,
- The technical differences of the Equinox catheter generate no new type of questions regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2001

Mr. Eben Gordon
Director of Regulatory Affairs and Quality Assurance
Micro Therapeutics, Inc.
2 Goodyear
Irvine, CA 92618

Re: K010162
Trade Name: Equinox™ Occlusion Balloon Catheter
Regulation Number: 870.4450
Regulatory Class: II (two)
Product Code: 74 MJN
Dated: April 4, 2001
Received: April 5, 2001

Dear Mr. Gordon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010162

Device Name: **Equinox™ Occlusion Balloon Catheter (System)**

Indications for Use: **The MTI Occlusion Balloon Catheter is indicated for use in the blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. The MTI Occlusion Balloon Catheter offers a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow.**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

Prescription Use_____ **OR** **Over the Counter Use**_____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010162